APPENDIX IV

DEC 1 1 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
TRUTHFUL AND ACCURATE STATEMENT

K013063

SUMMARY OF SAFETY AND EFFECTIVENESS

K013063

DEC 1 1 2001

COMPANY AND CONTACT PERSON

Medtronic Neurological
(Sullivan Lake Facility)
Columbia Heights, MN 55421
(763) 514-5068

Monaya Lee, Associate Product Regulations Manager

DEVICE NAME

Grip-lock™ Anchor

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Medtronic Twist-Lock Anchor (Part number 103963, or Model 3550TLA (kit) / 510(k): K972906); deemed substantially equivalent on February 6, 1998.

DESCRIPTION OF DEVICE

The Grip-lock™ Anchor is an implantable, sterile, nonpyrogenic anchor which has been designed to be compatible with existing Metronic Neurological leads. The design is based on existing anchors (Twist-Lock Anchor) currently marketed for use with Medtronic Neurological Leads.

The anchor is not pre-attached to the lead but is provided separate from the lead in a default-closed position. By squeezing the polysulfone wings together, the physician can slide the anchor onto the lead. Grooves in the polysulfone wings provide a location for the physician to grip the wings with rubber-shod forceps. The physician can readjust the position of the anchor by squeezing the polysulfone wings and sliding the anchor along the lead body to the desired position.

Once the anchor is in the desired position the physician can suture the anchor to tissue using the suture holes at the end of each polysulfone wing and the suture T attached to the anchor body.

The gripping mechanism of the Grip-lock™ Anchor is similar to that used by the Twist-Lock Anchor currently cleared for use with spinal cord stimulation (K972906).

STATEMENT OF INTENDED USE

The Medtronic Grip-lock™ Anchor is intended for use to facilitate Medtronic neurological lead fixation.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Medtronic Twist-Lock Anchor, Part Number 103953 or Model 3550TLA, is indicated as an alternate anchor accessory for use with Spinal Cord Stimulation (SCS) Systems for the treatment of chronic pain of the trunk or limbs. The Twist-Lock Anchor is only used with coiled conductor Medtronic Neurological Spinal Cord Stimulation leads with an outside diameter of 1.27 mm. All other uses are contraindicated.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification is being submitted for a modified neurological lead anchor. Other anchors, previously cleared by FDA, and currently marketed include:

- Medtronic Twist-Lock Anchor (Part number 103963, or Model 3550TLA(kit) / 510(k): K972906); was deemed substantially equivalent on February 6, 1998.
- Medtronic silicone anchors currently packaged in the lead kits approved for use with sacral nerve stimulation systems (P970004, approved September 29, 1997).

These Medtronic anchors are devices which are currently in commercial distribution. The Twist-Lock Anchor was deemed substantially equivalent on February 6, 1998. The silicone anchors are currently supplied as components in the lead kits used for sacral nerve stimulation (P970004, approved September 29, 1997).

In determining substantial equivalence of the Medtronic Grip-lock™ Anchor, the decision-making process follows the 510(k) "Substantial Equivalence" flow diagram as follows:

The Medtronic Grip-lock™ Anchor is being **"compared to the following Marketed Device"**:

- Medtronic Twist-Lock Anchor (K972906)

The Medtronic Grip-lock™ Anchor has the **"same intended uses"** as the:

- Medtronic Twist-Lock Anchor (K972906)

The proposed indication statement for the Grip-lock™ Anchor is "for use to facilitate Medtronic neurological lead fixation" while the indication for the Twist-Lock Anchor (K972906) is "for use with spinal cord stimulation systems for chronic intractable pain of the trunk and limbs." The intended use of both devices is to facilitate neurological lead fixation

The Medtronic Grip-lock™ Anchor has **"new technological characteristics (e.g., design, materials and manufacturing processes)"** from the current Medtronic Twist-Lock Anchor. The new technological characteristics are listed below:

- Materials : - Nitinol Band of the Grip-lock™ Anchor

  The Grip-lock Anchor is made primarily of polysulfone. A nitinol band encircles the anchor and serves as the closing mechanism of the anchor. Nitinol is commonly used is the medical device industry including use in cardiac stents.

- Closing mechanism of the Grip-lock™ Anchor: Default closed, polysulfone wings squeezed to open.

  The Grip-lock™ Anchor is provided in a "default-closed" configuration and is not pre-attached to the lead. When placing the anchor on the lead the physician can squeeze the polysulfone wings which open the anchor and allow the anchor to be moved along the length of the lead body. The Twist-Lock Anchor is also not pre-attached to the lead. When placing the anchor the physician twists the anchor to close it on the lead body.

These technological characteristics "**could affect the safety and effectiveness of the device**". However these **"new technological characteristics do not raise new types of safety or effectiveness questions"**. In addition, **"there are accepted scientific methods which exist for assessing effects of these new technological characteristics"**.

- Material analysis of nitinol was performed in accordance with ISO 10993-1, Biological Evaluation of Medical Devices - Part 1

"Performance data to assess the effects of these new technological characteristics" has been performed. The tests included;

- Adjustability and Placement on Lead
- Pull Force-Perpendicular
- Suture Hole Strength and Angular Pull Force
- Flex Life of Lead at Anchor

These **"performance data demonstrate"** that the Medtronic Grip-lock™ Anchor is substantially equivalent to the currently marketed Medtronic Twist-Lock Anchor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Ms. Monaya Krause
Associate Product Regulation Manager
Medtronic Functional Stimulation
800 53rd Avenue NE
Minneapolis, Minnesota 55421-1200

Re: K013063
Trade/Device Name: Grip-lock™ Anchor
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: September 10, 2001
Received: September 12, 2001

Dear Ms. Krause:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. **Indications For Use**

INDICATIONS FOR USE

510(k) Number: K013063

Device Name: Grip-lock™ Anchor

Indications for use:

The Medtronic Grip-lock™ Anchor is indicated for use to facilitate Medtronic neurological lead fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over-The-Counter-Use**

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices